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Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the VenoTrain curaflow 510(k) premarket notification.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the VenoTrain curaflow is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device.

Applicant:	Bauerfeind AG Triebeser Strasse 16 D-07937 Zeulenroda-Triebes Phone: +49 36628 661350 Facsimile: +49 36628 663153 Registration Number: 8010507
Date of submission:	June 1, 2011
Proprietary Name:	VenoTrain curaflow
Common Name:	Medical Support Stocking
Classification Status:	21 CFR 880.5780
Product Code:	DWL
Panel:	General Hospital

Predicate Devices
Bauerfeind's VenoTrain curaflow is substantially equivalent, for the purpose of this 510(k), to Torbot Vascular Compression Garments (K061411) and Elvarex compression garments (K963573).

Device Description
The VenoTrain curaflow compression garments help to prevent pooling of blood and fluid in the extremities by applying controlled pressure. The VenoTrain garments are flat knit using yarns made of nylon and spandex and then sewn together.

Intended Use
The VenoTrain curaflow compression garments are intended to be used to apply pressure to the extremities and are indicated for use in management of lymphedema and other edematous conditions, phlebitis, and vascular disorders.

Technological Characteristics and Substantial Equivalence
The VenoTrain curaflow is substantially equivalent to its predicates because it has the same intended use and very similar technological characteristics.

Both the VenoTrain curaflow and its predicates are intended to apply pressure, by elastic yarns that act circumferentially on the extremity, to manage lymphedema and other edematous conditions, phlebitis, and vascular disorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Ines Exner
Head of Quality and Regulatory Affairs
Bauerfeind AG
Triebeser Strasse 16
Zeulenroda-Triebes Germany 07937

OCT - 4 2011

Re: K111662
Trade/Device Name: VenoTrain curaflow
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: Class II
Product Code: DWL
Dated: September 16, 2011
Received: September 21, 2011

Dear Ms. Exner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

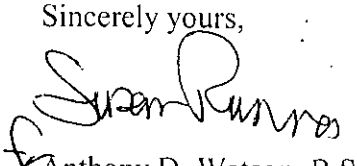
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indication for Use Statement

Indications for Use

510(k) Number (if known): not yet assigned K111662

Device Name: VenoTrain curaflow

Indications for Use: The VenoTrain curaflow compression garments are intended to be used to apply pressure to the extremities and are indicated for use in management of lymphedema and other edematous conditions, phlebitis, and vascular disorders.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/3/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111662